

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

VAN MEEL

Appl. No. *To be assigned*

Filed: Herewith

For: **Method for Monitoring the Effect of  
Cancer Therapies**

Confirmation No. N/A

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 0652.2300001/EKS/PSC

**Preliminary Amendment**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

It is respectfully requested that the following amendments to the specification and claims be entered in advance of substantive examination. This Amendment is provided in the following format:

- (A) A clean version of each replacement paragraph/section/claim along with clear instructions for entry;
- (B) Starting on a separate page, appropriate remarks and arguments. 37 C.F.R. § 1.115; and
- (C) Starting on a separate page, a marked-up version entitled: “Version with markings to show changes made.”

***In the specification:***

At page 1, line 3, please insert the following priority information:

The present application claims the benefit of provisional U.S. Appl. No. 60/223,372, filed August 7, 2000, which is herein incorporated by reference and EP 00 113 462.6, filed June 26, 2000 (in English), which is herein incorporated by reference.

***In the claims:***

Please replace pending claims 1 and 4-11 with the following claims 1 and 4-11:

1. A method for monitoring and evaluating the efficacy of a growth factor cancer drug in therapy, said method comprising the steps of:
  - a) collecting and preparing a sample containing cancer cells from an individual diagnosed for cancer and treated with a growth factor cancer drug,
  - b) determining the level of telomerase activity in said sample,
  - c) comparing the level of telomerase activity of said sample with the level determined in a sample in said individual before treatment or with a standard level of telomerase activity, and
  - d) correlating the level telomerase activity with the therapeutic effect of the growth factor cancer drug.
4. The method of claim 1, wherein the growth factor cancer drug is an inhibitor of a receptor from the epidermal growth factor receptor family or an inhibitor of the signaling pathway triggered by the activation of a receptor from the epidermal growth factor receptor family.

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5. The method of claim 1, wherein the growth factor cancer drug is an inhibitor of the epidermal growth factor.

6. The method of claim 1, wherein the growth factor cancer drug is an inhibitor of a receptor from the insulin-like growth factor receptor family or an inhibitor of the signaling pathway triggered by the activation of a receptor from the insulin-like growth factor receptor family.

7. The method of claim 1, wherein the growth factor cancer drug is an inhibitor of the insulin like growth factor.

8. The method of claim 1, wherein the growth factor cancer drug is an inhibitor of a receptor from the platelet-derived growth factor receptor family or an inhibitor of the signaling pathway triggered by the activation of a receptor from the platelet-derived growth factor receptor family.

9. The method of claim 1, wherein the growth factor cancer drug is an inhibitor of the platelet-derived growth factor.

10. The method of claim 1, wherein the growth factor cancer drug is an inhibitor of a receptor from the neurotrophic factors family or an inhibitor of the signaling pathway triggered by the activation of a receptor from the neurotrophic factors family.

11. The method of claim 1, wherein the growth factor cancer drug is an inhibitor of a component of a MAP kinase pathway.

Please cancel claims 14-16.

Please add the following new claim:

17. (New) The method of claim 1, wherein determining the level of telomerase activity in step (b) involves the use of a kit.

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***Remarks***

Upon entry of the amendments herein, claims 1-13 and 17 are pending the application with claim 1 being the sole independent claim.

***Conclusion***

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Eric K. Steffe  
Attorney for Applicants  
Registration No. 36,688

Date: 6/26/01  
1100 New York Avenue, N.W.  
Suite 600  
Washington, D.C. 20005-3934  
(202) 371-2600  
P104-29.wpd

**Version with markings to show changes made**

***In the specification:***

At page 1, line 3, after the following text has been inserted:

The present application claims the benefit of provisional U.S. Appl. No. 60/223,372, filed August 7, 2000, which is herein incorporated by reference and EP 00 113 462.6, filed June 26, 2000 (in English), which is herein incorporated by reference.

***In the claims:***

1. (Once amended) A method for monitoring and evaluating the efficacy of a growth factor cancer drug in therapy, said method comprising the steps of:
  - a) collecting and preparing a sample containing cancer cells from an individual diagnosed for cancer and treated with a growth factor cancer drug,
  - b) determining the level of telomerase activity in said sample,
  - c) comparing the level of telomerase activity of said sample with the level determined in a sample in said individual before treatment or with a standard level of telomerase activity, and
  - d) correlating the level telomerase activity with the therapeutic effect of the growth factor cancer drug.
  
4. (Once amended) The method of [any one of claims 1 to 3]claim 1, wherein the growth factor cancer drug is an inhibitor of a receptor from the epidermal growth factor

receptor family or an inhibitor of the signaling pathway triggered by the activation of a receptor from the epidermal growth factor receptor family.

5. (Once amended) The method of [any one of claims 1 to 3]claim 1, wherein the growth factor cancer drug is an inhibitor of the epidermal growth factor.

6. (Once amended) The method of [any one of claims 1 to 3]claim 1, wherein the growth factor cancer drug is an inhibitor of a receptor from the insulin-like growth factor receptor family or an inhibitor of the signaling pathway triggered by the activation of a receptor from the insulin-like growth factor receptor family.

7. (Once amended) The method of [any one of claims 1 to 3]claim 1, wherein the growth factor cancer drug is an inhibitor of the insulin like growth factor.

8. (Once amended) The method of [any one of claims 1 to 3]claim 1, wherein the growth factor cancer drug is an inhibitor of a receptor from the platelet-derived growth factor receptor family or an inhibitor of the signaling pathway triggered by the activation of a receptor from the platelet-derived growth factor receptor family.

9. (Once amended) The method of [any one of claims 1 to 3]claim 1, wherein the growth factor cancer drug is an inhibitor of the platelet-derived growth factor.

10. (Once amended) The method of [any one of claims 1 to 3]claim 1, wherein the growth factor cancer drug is an inhibitor of a receptor from the neurotrophic factors family or

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[illegible]

11. (Once amended) The method of [any one of claims 4, 6, 8 or 10]claim 1, wherein the growth factor cancer drug is an inhibitor of a component of a MAP kinase pathway.
14. (Cancelled)
15. (Cancelled)
16. (Cancelled)
17. (New) The method of claim 1, wherein determining the level of telomerase activity in step (b) involves the use of a kit.